AMERICAN ASSOCIATION of GRAIN INSPECTION and WEIGHING AGENCIES CONFERENCE

January 21 – 23, 2007

Las Vegas, Nevada

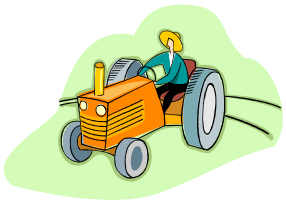
Who am I?
Or What am I doing here?

Beth Hayden

GIPSA Verification Programs Manager

- Hired by GIPSA, January 2004
- Came from Agricultural Marketing Service, National Organic Program
  - Accreditation Manager

  Prior to USDA – an Idaho Farmer



Good morning! I'm pleased to be here today and to begin a new project with you. My name is Beth Hayden, and I am the Verification Programs Manager for GIPSA. I'm responsible for several audit-based programs, and today I'm here to tell you about the audit-based program that has been developed for Official Service Providers.

I'll be explaining several changes and how they will affect the way you do business.

Before I begin, I'd like to share with you two important pieces of information about myself that, hopefully, will give you confidence in my ability help you through the changes that affect you directly.

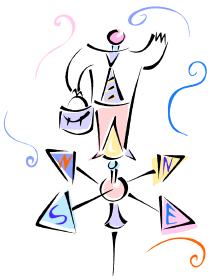
The first piece of information is that I was on the ground floor of changing the organic industry from an unregulated group of independent thinkers to a regulated, cohesive industry that now supplies the world with consistently- evaluated, organically produced food. I can tell you first hand that it wasn't an easy transition, but every certifying agent accredited by USDA is grateful for the management system they adopted under the organic regulation.

The second piece of information is that I came to Washington, DC, from my Idaho farm in 1989. That was a huge transition, and I know first hand how difficult change can be. Through that experience I learned that we can either embrace change and grow from it, or we can fight against change and stay where we are. I recommend the former attitude because change is a constant element in our all of our lives.

During the time I was changing my life, I had helpful people who guided and inspired me. I'd like to be one of those people for you, and we begin making changes

Topics / Changes

- GIPSA is changing
- Responsibilities will shift
- Reviews will be performed differently
- Assessments will be audits



On this slide is a list of the changes I'll be talking about.

GIPSA is changing. We are moving into the 21st century in the way we look at the organizations that provide service on our behalf. The most dramatic aspect of this change is a blueprint, the GIPSA Quality Standards, that will allow you to make your own decisions about they way you do business while still meeting the regulatory requirements for grain inspection and weighing service. This means that some of the responsibility will shift from GIPSA to you, but you will become more self-directed and self-reliant.

The new Quality Standard will be the basis for your reviews. The scope of the standard includes both legal requirements and business management practices. It does not address performance of inspection and weighing services. Those activities will be reviewed through centralized monitoring by another part of GIPSA.

The audits will be as objective as possible. This objectivity will be reflected in the reports you receive after the audit.

Before I go any farther – I want to address some very important facts.

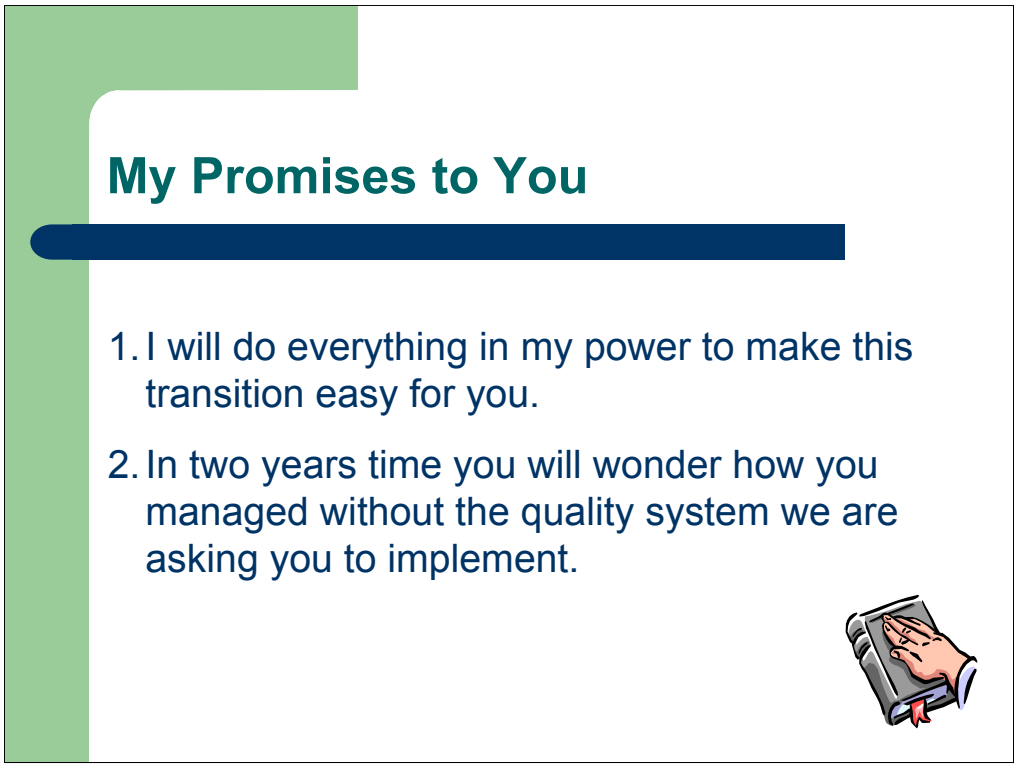
We are all new at this. It's the beginning of a new adventure! Through it, you can make your management systems work for you, and through GIPSA's quality system, we can make the entire program work for all of us.

However, we are not perfect. Because it's all new, and because we will have new management systems, we will be working toward perfection through continual improvement. Chances are we'll never be perfect; we can always find ways to improve!!

There will be glitches coming from GIPSA. We may come to you in a few weeks or months and tell you that we have to make some minor changes. On the other hand, when you begin with the new standard, you will make mistakes and you'll want to make changes or corrections.

So, we have to help one another by being patient, by sharing information, and by understanding that making a mistake is an opportunity to improve.

Please be patient with me and GIPSA as we implement this new, exciting program. Just like a ballet dancer, we'll all have to work hard to become a star performer.



As we approach this new experience, I want to make two promises to you. (Imagine that, someone from government making a promise --)

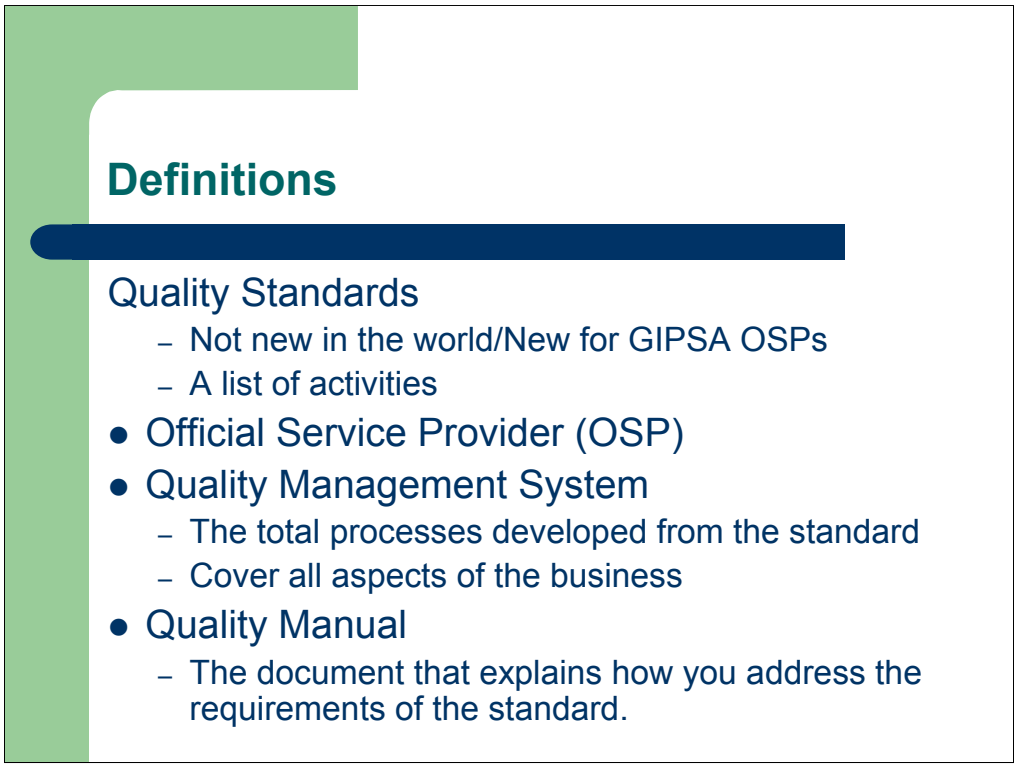
Here are the promises:

1. I will do everything in my power to make this transition easy for you.

2. In two years you will wonder how you managed without the quality management system we are asking you to implement.

These are my promises, and I do not make them lightly.

Now, let's get back to the changes I was telling you about.



I want to make certain that we all understand what I'm talking about before we go on. I've been throwing around some words that may be new to you.

All kinds of industries have developed Quality Standards; they are not new to the world. One of the most famous groups of quality standards are those developed under ISO. Perhaps you've heard of ISO 9000, a consensus standard developed by an international team for companies that produce a product or provide a service.

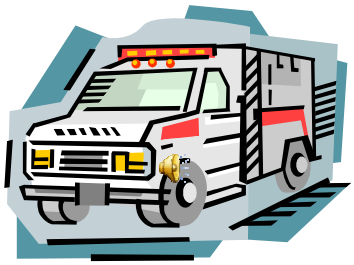
A group of knowledgeable people in GIPSA used ISO 9000 as a based, and then spent several months formulating a set of quality standards for any company or individual who performs work on behalf of GIPSA – Official Service Providers (OSPs). This may be a contractor who writes documents for GIPSA's use or facilitates re-organization, or it may be a company that provides grain inspection and weighing services.

GIPSA's Quality Standards are a list of activities that must be performed to provide confidence that the product or service meets GIPISA's requirements. These activities describe certain processes that happen in a business. They include Management Responsibility, Resource Management, Service Delivery (in your case grain inspection and weighing) and Measurement, Analysis, and Improvement. Taken together these processes create a management system. When I refer to a Quality Management System, I'm talking about processes listed in the standards that are implemented and fully functioning within a organization.

A Quality Manual is the document (book) you write that explains how your company meets the requirements of GIPSA's Quality Standards.

How will this help you?

- Self-reliance and confidence in the system
- A more active approach to management
- Support will come in a different way



Through the processes set out in the standards, you will become more self-reliant as you develop confidence in the system. The various processes define ways to ensure that you fully utilize all the resources you have available; that you monitor and measure your progress toward achieving your objectives; and that you provide your own internal evaluations, before GIPSA auditors call on you.

The system allows you to take control of events through effective management. You will become proactive rather than reactive.

And you will still receive support from the management system itself and from knowledgeable GIPSA staff who will help you resolve problems through the system you've set up.

I want to assure you, that the first couple of years will be a growing process and there will be plenty of mentoring, monitoring and corrective actions.

How will this help you?

- Auditing and oversight will be different
  - Audit will cover all business operations
  - Audit vs Review
  - Audit checklist – no scoring system
  - Audit report will reflect the audit checklist
  - Audits will cover compliance to laws and conformance to standards

Auditing and oversight will be different. And we're now going to explore some of those differences.

Audits will be to the Standard that reaches all aspects of the business

Audit vs. Review

Audit checklist – no scoring system

Audit report will reflect the audit checklist

Audits will cover compliance to laws and conformance to standards

General Legal Responsibilities are things you're already doing.

General Quality Standard Requirements are a broad summary of the entire standard that ties all the sections together. If you address the sections, you will address this

Documentation Requirements include the quality manual, control of documents and control of records.

Management Responsibility includes commitment to the Quality Management System and customer focus

Resource Management includes primarily personnel, infrastructure and work environment

Service Delivery sets up processes for delivering service and a plan for performing inspection and weighing service

Measurement, Monitoring and Improvement provides for internal audits, monitoring the processes as well as corrective and preventive actions.

You most likely are meeting most of these requirements, but you haven't written down how they are done. That is one of the uses for a quality manual and the documented procedures that you will develop – they put into writing what you do so that the process is repeatable when you're not there.

Audit vs. Review

- An audit verifies conformance/compliance
- Generally take 2 – 3 days
- A snap-shot in time
- Review in depth only as needed
- Sticks to the checklist

The purpose of an audit is to verify that your are in conformance or compliance. Auditors begin on the assumption that your are doing what you say in your quality manual.

You can expect audits to last 2 – 3 days for an average size operation. More complex operations will have longer audits.

Auditor's look at what you're doing at the present time. They review the processes you've implemented and records to ensure that your activities are repeatable. Primarily they want to know that you're doing what you told us in the quality manual. In a typical audit, the auditor will:

• review your procedure to ensure that it meets the Quality Standard requirement;

• watch the function being performed or interview the person responsible;

• review the records associated with the function; and

• check your internal audit to ensure that you have verified conformance/ compliance prior to the auditor's visit.

If everything checks out, the auditor will move to the next function. If there are problems, the audit will become more in depth.

The audit will be conducted using the audit checklist. The checklist will only change when the standard itself changes, and you will be notified if that happens.

Nonconformance and noncompliance will be pointed out when it is discovered. You will be able to take corrective action after the audit is completed.

Audit Checklist

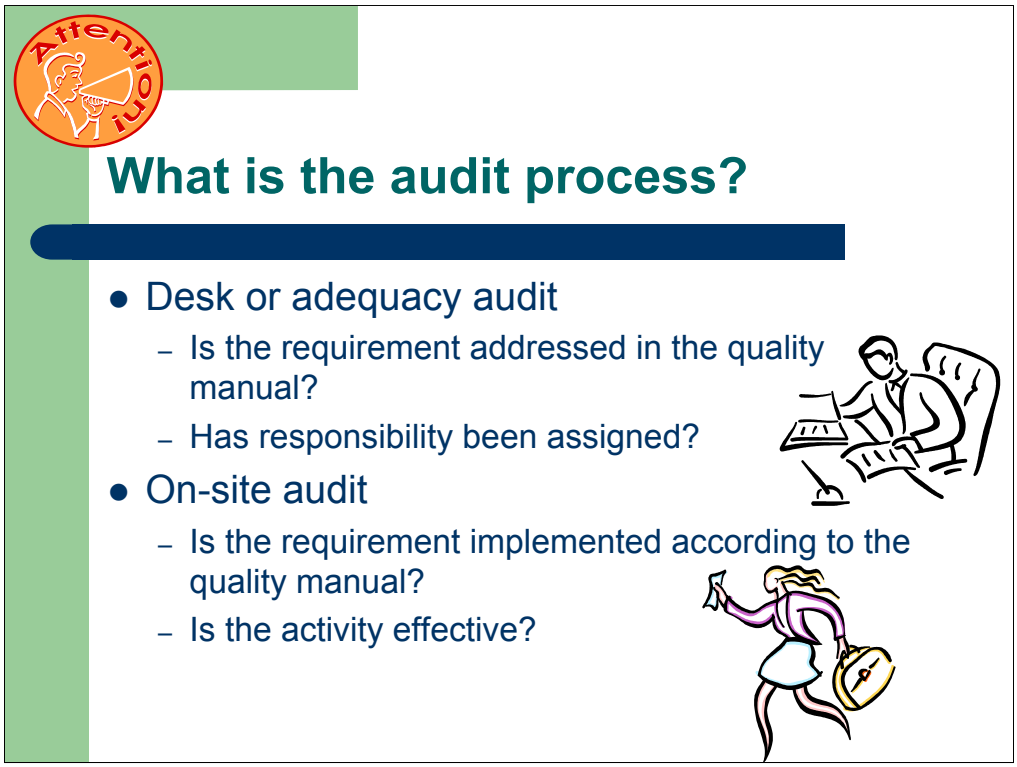
- Based EXACTLY on the standards
- No scoring system
- Looks at:
  - Are requirements addressed in the quality manual?
  - Who is responsible?
  - Is the requirement implemented?
  - Is it effective?

The audit checklist is based solely on the quality standards which include legal requirements. You will have access to both the standards and the checklist. There will no longer be a scoring system. Under the GIPSA Quality Standards, OSPs will either be in compliance and conformance or not. There will be no in between. This makes certain that audits are performed consistently.

The audit checklist looks at each requirement in four different ways:

1. Are the requirements addressed in the quality manual;
2. who is responsible [responsibility is assigned, not to point a finger when something is wrong, but to ensure that there is a person identified to perform a task];
3. is it implemented; and
4. is it effective?

The audit checklist and how OSPs are reviewed also will be covered later in this presentation.



I know that some of you may be feeling apprehensive by this time, so please pay close attention. This part of the presentation will lower your blood pressure.

The review process will be in two parts.

First is the desk or adequacy audit. For this part, you will send your quality manual to me for assessment on the first two sections of the checklist; i.e., is the requirement adequately addressed in the quality manual and has responsibility been assigned?

There will be a lot of back and forth during this audit. The auditor (who may be me) will ask questions for clarification or understanding and let you know if something is not adequately addressed. There will be no evaluation during this process – **no non-conformance or non-compliance**. The purpose will be to make certain that all elements of the requirements are addressed and to determine whether your organization is capable of meeting the standards when the manual is implemented. You will not see an auditor until this portion is completed. That doesn't mean you can't start implementation; you can begin the system right away.

The on-site audit will assess the second two parts of the checklist:

Is the requirement implemented? Is it effective? In other words, are you doing what you say in your quality manual?

Audit Report

- Based on the Checklist ONLY
- Clearly states non-conformance and non-compliance
- Recommends Approval or Denial (Suspension or Revocation)
- Includes observations or areas of improvement

The audit report will mirror the audit checklist EXACTLY!

It will address only findings from the audit and there will be no surprises. You will already have heard everything included in the report during the closing meeting of the audit.

Positive highlights will be included as well as non-compliance and non-conformance, but only those that were mentioned in the closing meeting will be included in the audit report.

A recommendation for approval or denial will be part of the report. There also will be circumstances when suspension or revocation are recommended. However, that would be only for flagrant violation of the law or repeated major non-conformance.

The reports also will contain observations or continuous improvement points. These are areas which need improvement. You'll want to take action on them because not improving them may lead to non-compliance or non-conformance.

Compliance and Conformance

- Compliance is the term used when speaking of adherence to laws.
- Conformance is the term used when speaking about adherence to quality standards
- Both will be covered in the assessment

What do I mean by compliance and conformance?

Compliance refers to activities that are required under the law. Failure to meet legal requirements will be taken very seriously (it is the law, after all).

Conformance refers to requirements of the quality standards. Non-conformance will be treated seriously in cases where the quality of the service is jeopardized.

Non-compliance and non-conformance will be assessed as “Major” and “Minor”. “Minor” means that only part of a requirement has been addressed. Corrective action must be made within 60 days of receipt of the audit report.

“Major” means that a requirement has been ignored or that it is not effectively implemented. Corrective action, or a plan of corrective action, must be provided to GIPSA within 15 days of receipt of the audit report.

An accumulation of “Minor” deficiencies may be considered a “Major” if the auditor observes that the Quality Management System is no longer effective.

The quality of grain inspection will not be assessed during these audits. It will be assessed by other people in GIPSA and in a different way. However, you will be required to have a plan dealing with the provision of inspection service. That plan will be assessed during the OSP audit.

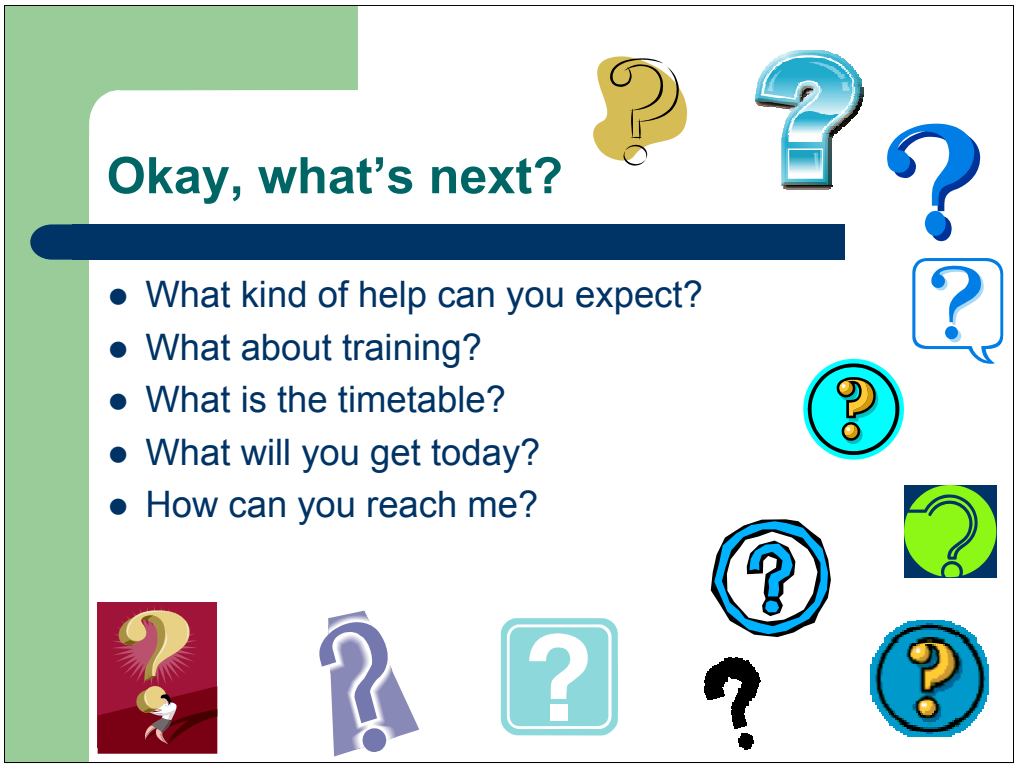
Auditors

- Auditors generally travel in pairs (unless there is a trainee)
- Audits last 2-3 days for an average size company
- Expect auditors to be mentors as well as evaluators

A word about the auditors. Auditors usually travel in pairs unless there is a trainee, and they don't stay very long.

For an average company an audit should last only 2 to 3 days. As I said earlier, more complex operations might take longer. However, there are accommodations for companies with multiple sites. Auditors may not visit every site every time.

In any event, you can expect auditors to serve as mentors through the provision of continuous improvement points or observations.



Now that I've talked some of the changes facing you, I'd like to address some questions you probably have:

What will you get today?

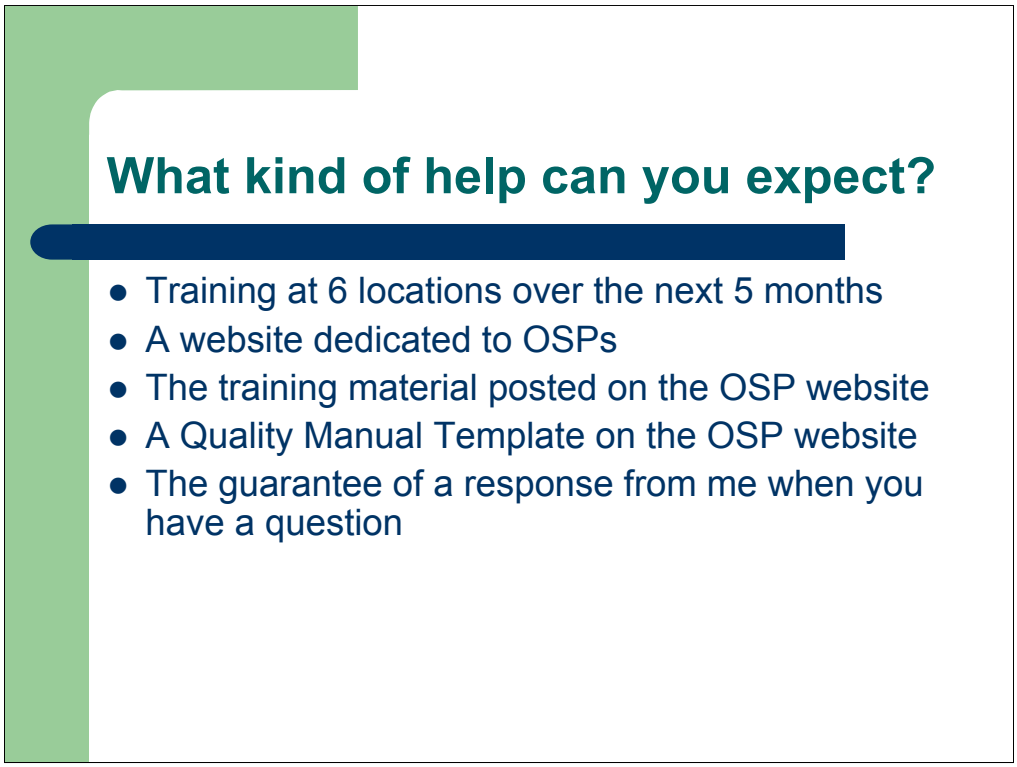
What about training?

What kind of help can you expect?

What is the timetable?

How can you reach me?

After I've addressed these questions, we'll have time for additional questions you might have.



Training will last for 3 days and be held in 6 locations over the next 5 months. I'll show you the schedule in a minute.

Training material will be posted on the website. It will include the training slides I'll show during the actual training sessions and two other training sessions I've provided to the grain industry. They are: "Creating and Documenting a Quality Management System" and "Implementing a Quality Management System". Both are based on ISO 9000, but they will still be helpful.

A Quality Manual Template will be provided on a CD and on the website. The template is a Microsoft Word document. In it I've done all the routine work for you; you have to provide the specific information about your organization. Think of this as a tool that helps you do a good job with your work.

You also have my guarantee that if you have a question, and you call me, I will be available to you. It may take a day or two for me to respond, but your questions will not go unanswered.

Training will cover the standards and writing the quality manual.

We are trying to make the training as economical as possible. I've discovered that we can accomplish a lot when participants travel in the morning and begin the training in the afternoon. That gives you the evening to absorb what you learned. It also gives time for homework.

So, on Day 1 you can travel in the morning and training will begin at 1:00 pm sharp. Day 2 will be a full day of training.

On the third day, training will end at noon. I will stay until evening, however, because you may have reason to speak with me. For example, if you've already started a quality manual, and you want me to give it a brief review, I'll stay behind to review it. Or if there was something in the training that you didn't understand, we'll talk about it until it's clear to you.

Training Locations

- Kansas City – Feb 21 – 23
- Indianapolis – April 3 -5
- Denver or *Dallas* – April 17 - 19
- Chicago – May 8 - 10
- Des Moines – May 22 - 24
- Nashville – June 5 - 7

Training locations are above: You'll have to send me an email, or call me, to register. I suggest that you register early because in some cases, participation will be limited.

The training locations are firm except for a choice between Denver and Dallas. The first thing we're going to do together is select this site for those who are located in the West or Northwest.

Please show hands for Denver [four hands shown]. For Dallas [2 hands shown].

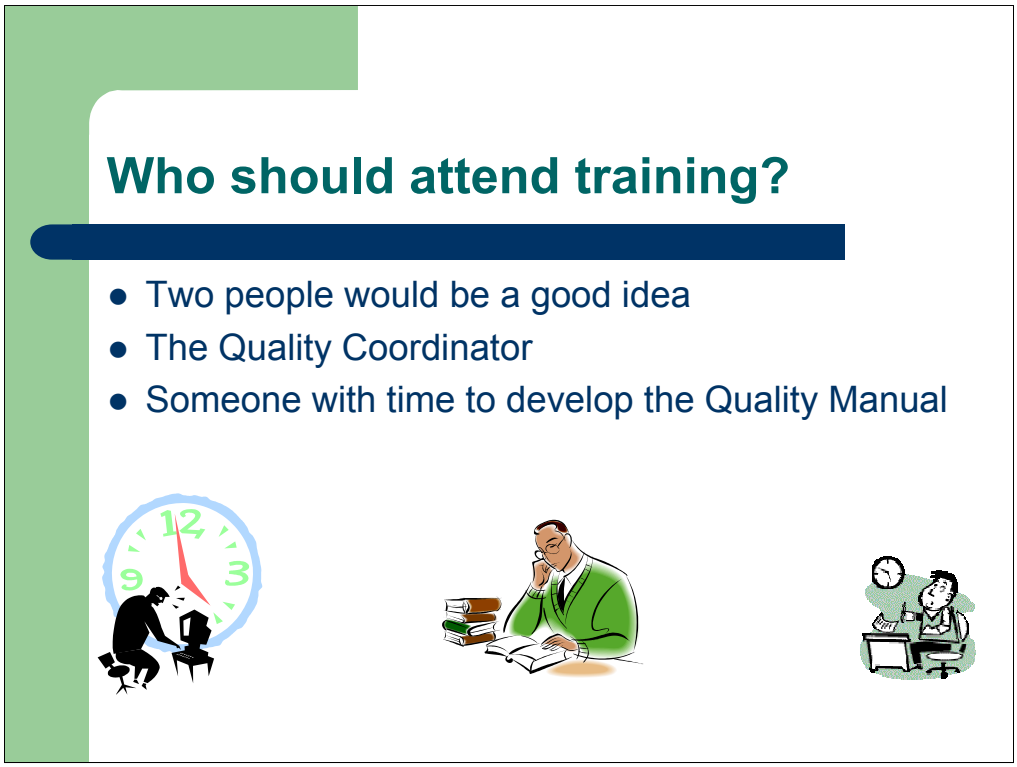
Okay, Denver is the location. When you get your handout, please cross out Dallas.

The Feb 21-23 – Kansas City NOAA Training Center, Near KC Airport & GIPSA Tec Center. I have space for 25 people.

April 3 – 5 – Indianapolis GSA Building space for 20

May 8 – 10 – (90% chance)Chicago FAA Building near Chicago OHare – 25 people

May 22 – 24 Des Moines Federal Building – 25 people



It would be a good idea to have two people attend the training, if possible. That way, you can share what you learned and "feed" off of one another's memory.

If that is not possible, then the next choice would be to send the Quality Coordinator. The GIPSA Quality Standard requires "The OSP top management must appoint a Quality Coordinator who, irrespective of other responsibilities, has responsibility and authority to ensure that processes needed for the QMS are established, implemented, and maintained.

This person cannot be the top manager.

Part of this person's responsibility will be Quality Manual development and maintenance.

The person also should be one who has time to devote to this project. It will take time to assess current activities and see where they fit into the Quality Standard. New procedures and processes will also have to be developed.

You should try to find someone like the fellow in the middle of this slide, not like the other two who are distracted and short of time.

What's the timetable?

- You'll need to sign up for training
- 6 months after training submit quality manual to GIPSA
- 12 months after training submit the internal audit results & management review minutes
- On-site audits will continue as scheduled until further notice

You'll need to sign up for training right away. You do not have to attend training, but it will be much easier for you if you can spend three days with me.

Six months after training, your quality manual will be due for a desk audit.

Organizations that decide not to participate in training will be required to turn in their quality manuals 6 months after the last training date.

12 months after training, you must submit the results of your internal audit and Quality Management System review. These two documents, must be provided for auditing annually from this time forward.

On-site audits will continue as scheduled until further notice. You will not be evaluated on the GIPSA Quality Standard until after the desk or adequacy audit has been completed.

We will, of course, take into consideration the time factors surrounding development and implementation of the quality system. In other words, we will not judge too harshly companies that have not had time to fully implement their quality program.

What do you get today?

- Hand out with important information
  - Training locations
  - My contact information
  - OSP website address for future information

Today you will receive a handout with two slides on it. [For website viewers, use the slides in this PowerPoint presentation for information.]

One has contact information with the address of your dedicated website. Check the website frequently – make it a bookmark or favorite so it's easy to get to.

Soon you will find posted on the website:

the Directive authorizing this change,

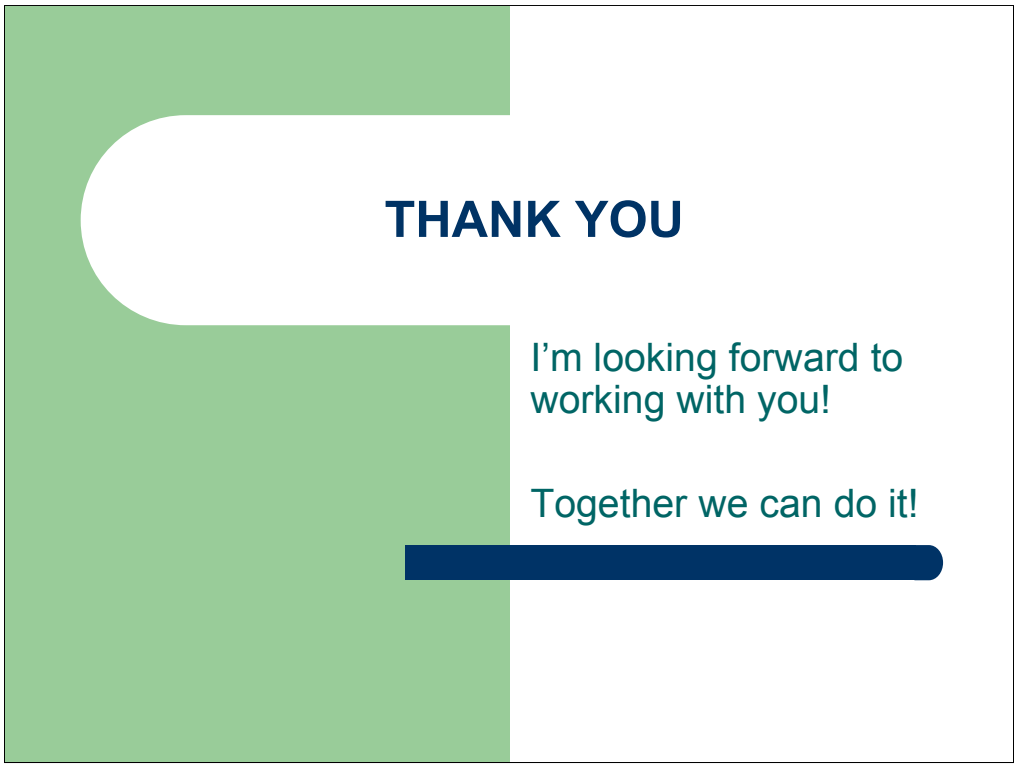
the GIPSA Quality Standard, and

a copy of this presentation.

You can review it to refresh the information you got today, and hold me and GIPSA to our word.

As we begin the training sessions, you will find posted on the website specific information about the training locations, the training material as well as a template for a quality manual.

In addition, I plan to have a Q & A section on the website. As questions come up, I'll try to post them with answers. Chances are that more than one person has the same question.



That concludes my presentation, except to say, “Thank you”. I’m looking forward to working with you.

Together with patience, kindness and good will, we can make our new quality management systems a success! Together we can do it!

Now, here is my contact information with the OSP website address. This information is also on the handout you will receive.

I'll be happy to take your questions now. Would someone please help me by jotting down the questions so we can have the beginning of the Q & A list?